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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/829,513 | 04/22/2004 | Jon A. Wolff | Mirus.010.01.1 | 7338 |
| 25032 | 7590 | 04/05/2006 | EXAMINER | |
| MIRUS CORPORATION 505 SOUTH ROSA RD MADISON, WI 53719 | | | LEAVITT, MARIA GOMEZ | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/829,513

Applicant(s)

WOLFF ET AL.

Examiner

Maria Leavitt

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Detailed Action

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Status of claims. The specification has been amended; claims 14, 16 and 23 have been amended and claims 1-13 and 17 has been cancelled by amendment dated March 01, 2006.

Response to arguments

3. Remaining rejections in response to Applicant arguments or amendments

35 U.S.C. 112, first paragraph, written

Claims 14-26 remains rejected under 35 U.S.C. 112, first paragraph.

In response to applicant's assertion (Remarks, p. 6) that the Action suggests on pages 4 and 8 a sufficient number of species to described a genus of chelator-polycationic polymers along with the description in the Specification, the comment is not found persuasive.

As indicated in the previous Office action, the as-filed specification only provides sufficient description of chelator-polycationic polymer, which must exhibit the ability to electrostatically bind to an expressible nucleic acid polymer (e.g., crown ether containing polymers and polycation systems containing crown ether) for use within the context of the claimed invention, e.g., enhance the delivery and expression of a desired nucleic acid. Applicant's claims as written encompass methods employing any other chelators other than crown ether e.g., systems containing atoms other than carbon in the ring of a heterocyclic compound, including cryptates,

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and non-cyclic polydentate molecules (p. 10, l. 27). Moreover, in Example 15, p. 31, the specification discloses merely examples of DNA-Polyacrylamidobenzo-18-crown-6/Poly-L-Lysine 6 Complexes, which are species of polycation systems containing crown ether.

Hence, rejection of claims 14-26 is maintained.

35 U.S.C. 112, first paragraph, enablement

In response to applicant's assertion (Remarks, p. 6) that amendments to claims 14, are sufficient to overcome the rejection based on the enablement requirement, the comment is not found persuasive.

The Examiner refers Applicants to the reasons of record, as disclosed in the previous office action. Moreover, Applicant has not addressed the broadest reasonable interpretation of claim 14 drawn to a process of delivering a polynucleotide to a cell wherein the delivery step encompasses not only the delivery of a chelator containing a polycation/nucleic acid polymer complex but also a nucleic acid by itself even when the step of associating the chelator to the nucleic acid polymer already has been carried out. Support for:

A process for delivering a polynucleotide to a cell comprising:

a) forming a complex consisting of a polynucleotide and a chelator, wherein electrostatic interaction of the chelator with one or more components of the complex requires the presence of a metal ion coordinated by the chelator; and

b) delivering the complex to the cell

is found throughout the disclosure of the specification and, specifically, on. p. 17, 26-27.

Hence, rejection of claims 14-26 is maintained.

35 U.S.C. 102(b)

In response to applicant's assertion (Remarks, p. 6) that Kayyen et al., teach a polychelator-polycation complex that is in contrast with the claimed current invention, which embraces forming a complex of DNA and amine-containing polycation and then associating a chelator with amine on the polycation, the comment is not found persuasive.

Kayyen discloses a polymeric molecule having a net positive charge comprising another polymeric molecule having a net negative charge (e.g. an anionic polymer (DNA)-cationic polymer complex, p. 7, lines 23-24) conjugated to a plurality of targeting moieties or physiological agents (p. 12, lines 1-3), including chelators bound to a contrast agents (page 10, paragraph 3; page 11, paragraph 2, pages 12 and 13, and pages 26-32). Further, Kayyem teaches that a plurality of chelators can be then added to the -NH₂ groups of the lysine side chains as linkers for binding to a plurality of contrast agents (page 10, paragraph 3). A major embodiment of the instant application is drawn to "a polycation is associated with a polyanion. ... A chelator or polychelator is then added to the polyion--polycation--polyanion complex Preferably, the polycation comprises a polyamine" (p. 17 lines 32-33 bridging to p. 18, lines 1-4). Absent evidence to the contrary, it is assumed that the complex/product of Kayyen has the same functionality of the claimed invention.

Hence, rejection of claims 14-26 is maintained.

35 USC 103(a)

Claims 14-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over

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Kayyem *et al.* taken with Hnatowich *et al.* (US Pat No. 5,980,861) for the reasons stated above in response to the 102 rejection.

Rejection, Obviousness Type Double Patenting-No secondary Reference(s)

Claims 14-26 remain rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-17 of U. S. Patent No. 6,818,626, filing date January 21, 1999.

In response to applicant's arguments that double patenting reflection seems to be base on the premise that the claims in U. S. Patent No. 6,818,626, encompass a polymer in which association of the polymer with a nucleic acid is dependent on the presence of metal cations whereas in the instant application association of the chelator with the nucleic acid is not dependent on the presence of metal cation, the comment is not found persuasive.

The Examiners notes the definition of the term chelator in the specification as "a polydentate ligand, a molecule that can occupy more than one site in the coordination sphere of an ion, particularly a metal ion, primary amine, or single proton". Hence the presence of a metal ion coordinated by the chelator is an obvious alternate embodiment of the invention because it is disclosed in the specification on p. 10, lines 25-27. Thus no secondary reference is necessary to make obvious the alternate embodiment as disclosed in the file-application.

Thus, Claims 14-26 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U. S. Patent No. 6,818,626, filing date January 21, 1999 for the reasons of record.

New Grounds of Rejection

Claim Rejections - 35 USC § 112- First paragraph- New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23 recites the limitation “a steric stabilizer”. Currently amended claim 23 embraces a polycationic molecule comprising a steric stabilizer. The specification discloses on p. 17, line 27, that “ the chelator is associated with a steric stabilizer”. A chelator is not a polycationic molecule but associates with a polycation, thus a polycationic molecule if associated with a chelator may consequently be associated a steric stabilizer. Thus, it is not clear that the Applicant was in possession of a genus of undefined polycationic molecule comprising a steric stabilizer at the time of filing.

Claim 23 will remain rejected until Applicant cancels all new matter.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

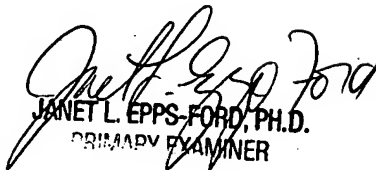
THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nguyen Dave can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner P/1633
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PRIMARY EXAMINER

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